K023303

OCT 2 9 2002

Section 7
Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. Identifying Information:
   - 1.1. Submitters Name: Medtronic AVE, Inc.
     37A Cherry Hill Drive
     Danvers, MA 01923
   - 1.2. Contact Person: Fred L. Boucher R.A.C.
     (978) 777-0042
2. Classification Name: Device, Coronary Saphenous Vein Graft, Temporary, for Embolization Protection (21 CFR Part 870.1250)
3. Proprietary Name: Export Aspiration Catheter
4. Name of Predicate Devices: GuardWire Temporary Occlusion and Aspiration System
5. Description:

   The Export Aspiration catheter is a dual lumen catheter for use with the GuardWire Temporary Occlusion and Aspiration System. The main (continuous) lumen of the catheter is the aspiration/infusion lumen while the smaller of the lumens is the guidewire lumen used to run over the GuardWire. The size of the wire lumen is sized so that the Export catheter may run over a 0.14-inch wire smoothly. Also, the wire lumen is designed as a single operator lumen, as such it is only present on a small section of the distal end of the catheter. The larger sized lumen is the aspiration lumen. A 20cc aspiration syringe is provided, as is an aspiration line. These are attached to the proximal end of the Export to facilitate blood and debris being evacuated from the site into the syringe.

6. Intended-Use:

   The Export Aspiration Catheter was designed to be used with the GuardWire Temporary Occlusion and Aspiration System. The Export Aspiration Catheter has the same indications for use as does the GuardWire temporary Occlusion and Aspiration System.

The Export Aspiration Catheter is indicated for use with the GuardWire Temporary Occlusion and Aspiration System in coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

7. Technology:

The Export Aspiration Catheters are manufactured in the same manner, using the same processes and materials, as the Export Aspiration Catheter that is contained in the GuardWire Temporary Occlusion and Aspiration System; the legally marketed predicate device. In addition to being technologically the same as the predicate device, the indications for use have not changed.

The Export Aspiration Catheter is substantially equivalent to the Export Aspiration Catheter contained in the GuardWire Temporary Occlusion and Aspiration System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2002

Medtronic, Inc.
c/o Mr. Fred L. Boucher, RAC
Sr. Regulatory Affairs Manager
37A Cherry Hill Drive
Danvers, MA 01923

Re: K023303
Trade Name: Export Aspiration Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Device, Coronary Saphenous Vein Graft, Temporary, for Embolization Protection
Regulatory Class: Class II (two)
Product Code: NFA
Dated: October 2, 2002
Received: October 3, 2002

Dear Mr. Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023303

Device Name: Export Aspiration Catheter

Indications for Use:

The Export Aspiration Catheter is indicated for use with the GuardWire Temporary Occlusion and Aspiration System in coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K023303